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Response (with RCE)

**Remarks**

This is in response to the Office Action mailed March 28, 2005.

Reconsideration of the pending Claims 1, 2, 4-6, 11, 35, 40, 42-44, and 48-57 is respectfully requested.

Claims 9, 10, 39, and 41 have been canceled.

Claims 1, 5, 6, 40, 42-44, 50, 51, and 53-57 have been amended to better define the subject matter claimed.

Support for the phrase "concentration of the odorants being greater than an average normal threshold concentration of the odorants...at about 25-55 decismel units" is in original Claims 9-10 (and 16-17) ("9. The method of claim 1, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant. 10. The method of claim 9, wherein the concentration of the odorant is at about 25-55 decismel units.")

Further support for the amendments is in the specification at page 5, lines 3-6 ("In the use of odorants to stimulate or decrease vaginal flow, it is preferred that the subject individual *is presented with the odorant at a suprathreshold concentration (e.g., about 25-55 decismel units)*, but not irritative level, and inhales the odorant for about 1-3 minutes."), page 5, lines 7-9 ("An odorant is presented at a *suprathreshold level when the decismel level or concentration of the odorant is beyond that needed to be detected by a normosmic individual.*"), page 6, lines 18-20 ("In the art, a *"normosmic" individual is one who can detect the odor of a substance without irritant sensations when the odorant is presented within the range of its average normal threshold.*"). In addition, the Examiner is directed to the specification at page 6, lines 10-11 ("Ranges of the *average normal threshold* for various odorant substances can be found in the art, for example, Amoore and O'Neill,...").

The Examiner is also directed to the discussion below regarding the understanding in the art of the term "suprathreshold" as being a concentration of odorants that is greater than the mean or average threshold concentration – a concentration of about 25-55 decismels being an increased amount of the mean normal threshold concentration.

Support for the amendment to Claims 42 and 50 ("capped vessel having a tip impregnated with the odorant composition") is in the specification at page 7, lines 9-10 and original Claim 22.

Applicant requests reconsideration of Claim 53, which has been amended to recite the odorant composition as a mixture of odorants.

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No new matter has been added with the amendments, which are clearly supported in the specification as originally filed, as provided above. The amendments are intended to merely clarify language used in the claims and/or the subject matter claimed, and the scope of the claims is intended to be the same as after the amendments as it was before the amendments.

The objection to Claims 48 and 49 is acknowledged.

**Rejection of Claims under 35 U.S.C. §§ 102(b)/103(a) (Poan/McMath)**

The Examiner maintains the rejection of Claims 1, 2, 4-6, 9, 10, 35, 41, 43, 44, and 50 as anticipated by the International Product Alert bulletin entitled "Poan Washable Cold Cream Manufacture: Kurabara Honpo Category: Beauty Skin Care" (01 June 1994 - PROMT Abstract) ("Poan"), or by McMath from Adweek's Marketing Week entitled "The Skin Trade Goes Natural" (27 August 1990 - PROMT Abstract) ("McMath"). At page 7, the Examiner also maintains the rejection of Claims 1, 2, 4-6, 9-11, 35, and 39-44, as obvious over Poan or McMath. Insofar as these rejections are maintained with respect to the claims as amended, these rejections are respectfully traversed.

The Examiner maintains that it would be inherent that the described commercial skin cream products would inherently provide odorant concentrations within the levels instantly claimed.

Claims 6, 43, and 53 have been amended to recite that the odorant composition is a *liquid*, while Claims 1, 5, and 44 have been amended to recite that the composition is administered from a blister pack, a scratch-and-sniff odor patch, a scented cloth, and/or a spray device, Claim 53 has been amended to recite that the liquid composition is delivered from a spray device, capped vessel, and/or blister pack, and Claim 50 has been amended to recite delivery from a capped vessel with a tip impregnated with the odorant composition. Claim 56 has been amended to recite that the *licorice-based and cucumber* odorant composition is in the form of microcapsules administered from delivery device comprising a scratch-and-sniff odor patch.

By comparison, the cited references describe a *cream* – and none of the delivery devices.

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In addition, Claims 1, 2, 4-6, 11, 40, 42-44, and 48-57 have been amended to more clearly recite the concentration of the odorants in the composition – by clarifying and further distinguishing the term "suprathreshold concentration" in the claims.

A "suprathreshold" amount of an odorant is not merely the level detectable by a normosmic individual. A "suprathreshold concentration" is, *by definition*, a concentration that is *higher than* the average normal threshold concentration of an odorant – and, as recited in the claims, is at about 25-55 decismel units – a concentration that is many times higher than the average normal threshold concentration of the odorants.

The Examiner is directed to the supporting passages provided above for this amendment to the claims. In particular, the Examiner is directed to original Claims 9-10, which state as follows:

9. The method of claim 1, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.
10. The method of claim 9, wherein the concentration of the odorant is at about 25-55 decismel units."

A suprathreshold concentration is a definitive amount of the odorant – which can be objectively measured by known methods in the art. It is not merely the level detectable by a normosmic individual. It is a level that is above the average normal threshold concentration of an odorant. And in the instant claims – this is a level that is at 25-55 decismel units – where the normal threshold concentration is set at 0 decismel units, and thus, a concentration that is many times higher than the average or mean normal threshold concentration of the odorants.

Aside from Applicant's disclosure (as discussed above with regard to the claim amendments), the Examiner is respectfully directed to the disclosures in the following publications (copy enclosed) for a further supporting description of a suprathreshold concentration of an odorant – and the meaning of a decismel unit in the suprathreshold range in relation to the average threshold concentration of an odorant.

The decismel units in the suprathreshold range are an "X"-fold increase over the mean or average threshold concentration of an odorant. The Examiner is respectfully directed to the following (emphasis added):

- a) **USP 6,325,475** (Hayes et al.; "Devices for Presenting Airborne Materials to the Nose") at col. 8, lines 54-66, and col. 20 at lines 55-65 (emphasis added):

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...For threshold testing of the sense of smell, **3-4 orders of magnitude** dynamic range (**60-80 decismels**), where:

$$1 \text{ decimel} = \frac{\log_{10} [\text{odor concentration}]}{20}$$

are needed.

For a typical logarithmic series of test substance intensities, the dispensers 12 can dispense increasing masses of test substance by increasing the number of drops dispensed. Jetting at 1 to 10,000 drops/second, a single jet 12 can dispense over a 4 log-unit range of test substance intensity in 1 second. For greater temporal compression, jets 12 with differing concentrations can be used. For most test substances, a **range of 40 decismels (100-fold concentration range)** includes the thresholds of about 98% of all subjects (i.e.,  $\pm 2$  standard deviations), so that 80 decismels (10,000-fold) is more than an adequate dynamic range for the system.

- b) USP 5,380,765 (Hirsch; "Chemosensory olfactory assay for psychiatric disorders") at cols. 7-8, bridging paragraph (emphasis added):

Odor thresholds are expressed on the "decimel scale". **The mean threshold concentration of a chemosensory agent detected by a control group of 20-year olds is set at the 0 value.** A decimel is calculated by dividing the concentration of the chemosensory agent detected by the patient to the **normal threshold concentration** (using the published value or empirically determining the value) and then taking the logarithm of the quotient. The logarithm of the quotient is then multiplied by 20 to obtain the decimel value... **An increase in the threshold concentration value over the mean threshold concentration value of twofold corresponds to 6 decismels.** The suggested thresholds for hyposmia are 30 ds and of functional anosmia at 54 ds. The normal mean threshold values for each chemosensory agent are known and can be used to convert the threshold concentration into decismels. ...

- c) Prudhomme et al., Acute-Onset Persistent Olfactory Deficit Resulting from Multiple Overexposures to Ammonia Vapor at Work, *J Am Board Fam Pract* 11(1):66-69 (1998) ([www.medscape.com/viewarticle/417766](http://www.medscape.com/viewarticle/417766) at page 3 of 4 (emphasis added):

\* Decismels (dS) are defined as  $20 \log (\text{test concentration/reference concentration})$ , where the reference concentration is the average odor threshold in a reference population. Thus, a score of 40 dS indicates that the patient's odor detection threshold was at a test concentration 100 times the population average for the compound employed.

As noted above, 6 decismels corresponds to a 2-fold increase over the mean or average threshold concentration value. Forty (40) decismels corresponds to a concentration that is 100 times the average odor threshold. Thus, the "25-55 decimel units" amount recited in the claims is *much higher* than the mean or average threshold concentration of the odorants.

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The Poan and McMath compositions are *creams* – and the descriptions of the Poan and the McMath creams merely provides a list of several ingredients – with no recited concentrations – or delivery systems as recited in the claims.

There is no teaching in either reference that either product contains a *suprathreshold amount* of a cucumber and licorice odorant — i.e., a concentration of the odorant that is beyond the mean (average) normal threshold concentration at the recited decismel units. Nor is there any motivation for either product to be prepared with such a concentration of odorants as provided in Applicant's composition.

The cream products described by the cited references would not inherently contain the odorants in a *suprathreshold amount* as recited in the claims, and would not inherently provide the recited effect of altering blood flow to the vagina of the female.

The cited references do not teach or suggest Applicant's method of altering blood flow to the vagina of a female individual by inhalation of a suprathreshold but not irritating concentration of the recited odorant compositions. Rather, the cited references merely teach a cream product that contains cucumber and licorice extracts in amounts to provide a moisturizing effect on the skin.

Accordingly, in view of the amendments to the claims and for the foregoing reasons, withdrawal of the rejection of the claims based on the cited references is respectfully requested.

#### **Rejection of Claims under 35 U.S.C. § 102(b) (Yankee Candle)**

The Examiner maintains the rejection of Claims 1, 2, 4, 5, 9, 10, 11, 44, 50, 51, and 54-56 as anticipated by a female individual inhaling a mixture of scents (odorants) provided by the candle products on display within a Yankee Candle Company, Inc. store, (citing to the internet website). Insofar as this rejection is maintained with respect to the claims as amended, this rejection is respectfully traversed.

The Examiner maintains that the odorants released from the scented candles within the store (e.g., cucumber, banana nut bread, lavender, pumpkin pie, etc.) would inherently provide a suprathreshold but not irritant amount of the inhaled odors citing to "the definition on page 5, lines 8-19, of the instant specification," and that the claimed functional effect would be inherent.

The Examiner further indicated that limiting the claims to provide the odorant mixtures within certain types of delivery devices and/or containers would overcome the art rejection.

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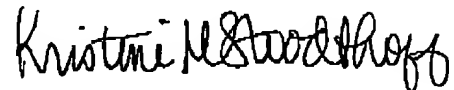
Claims 1, 5, 44, 51, 54, and 55 have been amended as suggested by the Examiner. Claim 50 has been amended to recite that the odorant composition is administered from a delivery device comprising a capped vessel having a tip impregnated with the odorant composition. Claim 56 has been amended to recite that the *licorice-based and cucumber* odorant composition is in the form of microcapsules administered from a delivery device comprising a scratch-and-sniff odor patch.

Accordingly, withdrawal of the rejection of the claims based on the Yankee Candle reference is respectfully requested.

**Extension of Term.** The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply. Applicant believes that a two (2) month extension of term is required. The Examiner is authorized to charge the required fee(s) to Account No. 23-2053. Large entity fees apply. If an additional extension of time is required, please consider this a petition therefor and charge the required fee(s) to Account No. 23-2053.

Applicant requests reconsideration of the amended claims. Applicant believes that the claims are in condition for allowance, and notification to that effect is respectfully requested. The Examiner is urged to telephone the undersigned Attorney if any questions should arise or further discussion would expedite the examination of the application.

Respectfully submitted,



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